



**Attorney General Colberg Announces Settlement
With Maker of Implantable Defibrillators**

FOR IMMEDIATE RELEASE: August 30, 2007

(Anchorage, AK) Today Attorney General Talis Colberg announced that he and 35 other state attorneys general reached a settlement with Guidant Corporation regarding the sale of a type of Implantable Cardioverter Defibrillator (ICD). ICDs are medical devices that doctors surgically implant in a patient's chest to monitor for abnormal heart rhythms. If the heart stops, the ICD delivers a small jolt of electricity to start the heart functioning again. The ICD at issue in the settlement is the Ventak Prizm 2 DR Model 1861 (Prizm). Guidant, a subsidiary of the Boston Scientific Corporation, is the third largest seller of ICDs in the country.

Guidant has agreed to implement ICD safety programs, publicly report safety information about the devices, and pay \$16,750,000.00 to the states involved in the settlement.

The attorneys general began investigating Guidant when they learned the company made modifications to the Prizm to correct a wiring problem, but Guidant continued to sell unmodified Prizms. The wiring problem identified by Guidant could cause the ICD to short circuit which could prevent the unit from delivering a life-saving jump-start to a patient's heart when needed. Guidant did not inform physicians or the public until May 2005 that it had continued to sell unmodified Prizms in 2002 and 2003.

Under the settlement, Guidant also agreed to:

- Establish a patient safety advisory board consisting of independent experts to evaluate data concerning ICD performance;
- Establish a patient safety officer position, staffed by a physician whose primary responsibility is to advance ICD patient safety;
- Clearly disclose and disseminate to the public information including: worldwide failure data, survival probability estimates, and current information in the event of an FDA recall of any ICD;
- Post a notice on its website within 30 days of any modification to any of its

- ICDs to correct a failure pattern;
- Solicit the return of out-of-service ICDs; and,
- Maintain a data system to track the serial numbers, implant dates and explant dates of all ICDs Guidant distributes in the United States;

Guidant currently has a warranty program that allows consumers to replace their Prizms with a new device at no cost and provides reimbursement of up to \$2,500.00 for out-of-pocket expenses. As part of the settlement, Guidant will extend this warranty program for an additional six months. Also, the states will use up to \$1,000,000 of the \$16,750,000.00 payment to reimburse consumers in the warranty program for expenses they incurred beyond \$2,500.00.

Alaska's share of the \$16,750,000.00 is \$390,000, which will be used to fund consumer education and enforcement of consumer protection laws in the state. Guidant does not admit to any wrongdoing.

For questions about the settlement, please contact Assistant Attorney General Cynthia Drinkwater at (907) 269-5200.